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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,720	02/15/2001	Klaus Abraham-Fuchs	P00,1222	2613

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EXAMINER
MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
1631	6

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,720	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	Channing S. Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 5, filed 02 June 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-16.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 3, 4, 9, 10 and all claims dependent therefrom recite the term "expert" which is vague and indefinite. Applicants' present the following with respect to the expert system and the expert rules therein (Paper No. 5, filed 02 June 2003, page 10, lines 3-17), "The details, or the specific purpose, of the evaluation system that includes an expert system are not important to the use and operation of the subject matter of claims 1 and 9. It is only necessary that information be gathered from a plurality of disposable biochips from a plurality of patients, and that this information include multiple biomolecular markers, and that the point of care

information be obtained from at least one of the biochips and that clinical data be obtained which is composed of a diagnostic result and the additional information set forth in the claims, and that the rules employed by the evaluation system be modified using all point of care raw data and all of the clinical data. As noted above, the goal of producing the modified expert rule is for the expert rule to have improved diagnostic specificity compared to initial expert rules." It is noted the preamble and body, for example of claim 1 (lines 1-2 and 27-31), recites "A network for creating a modified expert rule in an expert system from medical data compiled in a clinical study." and "said evaluation system comprising an expert system operating according to expert rules and creating a modified expert rule with improved diagnostic specificity, compared to said expert rules, using all of said point of care raw data and all of said clinical data." Applicants' further present "The exact nature of the expert rules, and the goal or intended result that they are to achieve, are not important to the subject matter of the invention. It is only important that at least one of the original rules be modified so as to improve the diagnostic specificity. This is an easily ascertainable standard." It is therefore unclear what the term "expert" is intended to limit in the claim. Clarification of the metes and bounds, via clearer claim language is requested.

Claim 9 and all claims dependent therefrom are found confusing wherein the preamble (line 1) recites a "new expert rule", however, the body of the claim is directed to a "modified expert rule" (line 30). This appears to be an oversight, however, if the claims are intended to be directed to new rules then the enablement rejection set forth in the prior office action would still apply. It is noted Applicants indicated in Paper No. 5, filed 02 June 2003, that the term "new expert rule" has been replaced in the present amendment by "modified expert rule", however,

claim 9 is not representative of said amendment. Clarification of the metes and bounds, via clearer claim language is requested.

LACK OF ANTECEDENT BASIS

Claims 11 (line 2) and 12 (line 2) recites the limitation "new rule". There is no clear antecedent basis for this limitation in claims 9 and 10, which claims 11 and 12 depends from. Clarification is requested.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Anderson et al. (U.S. Patent Number 6,394,952 B1) taken in view of Mendoza et al.

Anderson et al. discloses a system and methods for processing patient data at a point of care to provide for medical diagnosis or risk assessment of a patient (Abstract). The patient data is to include information from physical and biochemical tests, such as medical records or history (i.e. electronic patient records), immunoassays, chemical assays, nucleic acid assays, calorimetric assays, fluorometric assays, chemiluminescent and bioluminescent assays, electrocardiograms, X-rays and other such tests (Column 2, lines 39-41; Column 9, lines 21-33 and 57-65). The inventors discuss various types of assays and provide an example of an immunoassay test (i.e. ELISA) and device wherein antibodies that react with a target analyte and/or a detectable label system (Columns 10-11, beginning on line 9; and Figures 1-5). The invention is to be employed

at various point of care facilities, such as in emergency rooms, operating rooms, hospital laboratories and other clinical laboratories, doctor's offices, in the field, or in any situation in which a rapid and accurate result is desired. Anderson et al. includes a decision-support system (i.e. neural network) for evaluating and assessing patient data through integration with other patient information (i.e. including documents and information in medical records), wherein the decision-support system as any system that can be trained on data to classify the input data and then subsequently used with new input data to make decisions based on the training data (i.e. expert system/rules) (Column 2, lines 26-32; Columns 7-8, beginning on line 52; and Column 23, lines 16-43). The patient data or information is analyzed by the decision-support systems to identify important or relevant variables and decision-support systems are trained on the patient data. Patient data are augmented by biochemical test data or results to refine performance. The resulting decision-support systems are employed to evaluate specific observation values and test data to guide the development of biochemical or other diagnostic tests, to assess a course of treatment, to identify new diagnostic tests and disease markers, to identify useful therapies, and to provide the decision-support functionality for the test. Methods for identification of important input variables for a medical diagnostic tests for use in training the decision-support systems to guide the development of the tests, for improving the sensitivity and specificity of such tests, and for selecting diagnostic tests that improve overall diagnosis of, or potential for, a disease state and that permit the effectiveness of a selected therapeutic protocol to be assessed are also provided. (Columns 31-32, beginning on line 34). The software and instrument components of the invention can be packaged singly or, alternatively, the software can be contained in a remote computer so that the test data obtained at a point of care can be sent electronically to a processing

center for evaluation (Column 2, lines 32-38). However, Anderson et al. fails to specifically indicate a "biochip".

Mendoza et al. describes "a new generation biochip...capable of supporting high-throughput multiplexed enzyme-linked immunosorbent assays" and evaluates "the feasibility of immobilizing protein antigens on glass surfaces in a miniaturized format with a new type of array printer and specifically imaging the printed antigens in a highly parallel, multiplexed ELISA format compatible with high-throughput analysis systems" (pages 778-788; particularly the Abstract and page 788, left column, lines 29-36). Additionally, Mendoza et al. makes note of DNA based arrays (i.e. DNA biochips) in high-throughput genotyping, differential gene expression, mutation detection and DNA sequencing (page 778, middle column, lines 3-12). It is noted that the instant application provides for a broadly encompassing definition of a "biochip" as a marker array, wherein "almost all known types of biomolecular markers (e.g. DNA fragments, proteins, enzymes, antibodies, etc) can be measured simultaneously on the same chip" (page 2, lines 18-23; and pages 4-5, beginning on line 14). Mendoza et al. clearly discloses such a biochip. However, Mendoza fails to describe a network for creating a modified expert rule in an expert system from medical data.

Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Anderson et al. (system and methods for processing patient data at a point of care to provide for medical diagnosis or risk assessment of a patient) with Mendoza et al., since Mendoza et al. states "chip-based formats promise to increase clinical diagnostic throughput in cancer and infectious disease diagnostics while simultaneously reducing cost" (page 788, middle column, 46-49). Further, Anderson et al. indicate a variety patient

information/data from assays (i.e. immunoassay) may be utilized in the system and method (Column 2, lines 39-41; Column 9, lines 21-33 and 57-65). Thus, one of ordinary skill in the art would be motivated to utilize a "biochip" to increase the rate of clinical diagnosis and reduce cost.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: September 4, 2003

Examiner Initials: CSM

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